

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MURGITROYD & COMPANY  
Chartered Patent Agents  
373 Scotland Street  
Glasgow G5 8QA  
ROYAUME-UNI

Date of mailing (day/month/year) 26 October 2001 (26.10.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference P26119A/GWO	
International application No. PCT/GB00/01725	International filing date (day/month/year) 05 May 2000 (05.05.00)

1. The following indications appeared on record concerning:		
<input checked="" type="checkbox"/> the applicant	<input type="checkbox"/> the inventor	<input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address UNIVERSITY OF ULSTER Faculty of Engineering Newtonabbey County Antrim BT37 0QB United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input checked="" type="checkbox"/> the person	<input checked="" type="checkbox"/> the name	<input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address UUTECH LIMITED University House Cromore Road Corelaine Co Antrim Northern Ireland, BT52 1SA United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
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<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned	
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Idhir BRITEL
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
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 United States Patent and Trademark  
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 in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 18 January 2001 (18.01.01)	
<b>International application No.</b> PCT/GB00/01725	<b>Applicant's or agent's file reference</b> P26119A/GWO
<b>International filing date (day/month/year)</b> 05 May 2000 (05.05.00)	<b>Priority date (day/month/year)</b> 06 May 1999 (06.05.99)
<b>Applicant</b> ANDERSON, John, McCune et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 15 December 2000 (15.12.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☐ was  
☒ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Juan Cruz Telephone No.: (41-22) 338.83.38
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## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>P26119A/GWO</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 00/ 01725</b>	International filing date (day/month/year) <b>05/05/2000</b>	(Earliest) Priority Date (day/month/year) <b>06/05/1999</b>
Applicant  <b>UNIVERSITY OF ULSTER et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1

☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 00/01725

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61N1/378

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

INSPEC, EPO-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 796 221 A (HAGFORS N) 12 March 1974 (1974-03-12) column 2, line 52-65 ---	1
A	US 4 549 547 A (REDKA WILLIAM ET AL) 29 October 1985 (1985-10-29) column 1, line 67 -column 2, line 37 ---	1
A	US 5 735 887 A (ECHARRI ROBERT ET AL) 7 April 1998 (1998-04-07) column 9, line 9-17 ---	1
A	US 5 411 537 A (MUNSHI MOHAMMED Z ET AL) 2 May 1995 (1995-05-02) abstract -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

26 September 2000

Date of mailing of the international search report

04/10/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Grossmann, C.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/GB 00/01725

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 3796221	A	12-03-1974	NONE	
US 4549547	A	29-10-1985	NONE	
US 5735887	A	07-04-1998	NONE	
US 5411537	A	02-05-1995	NONE	



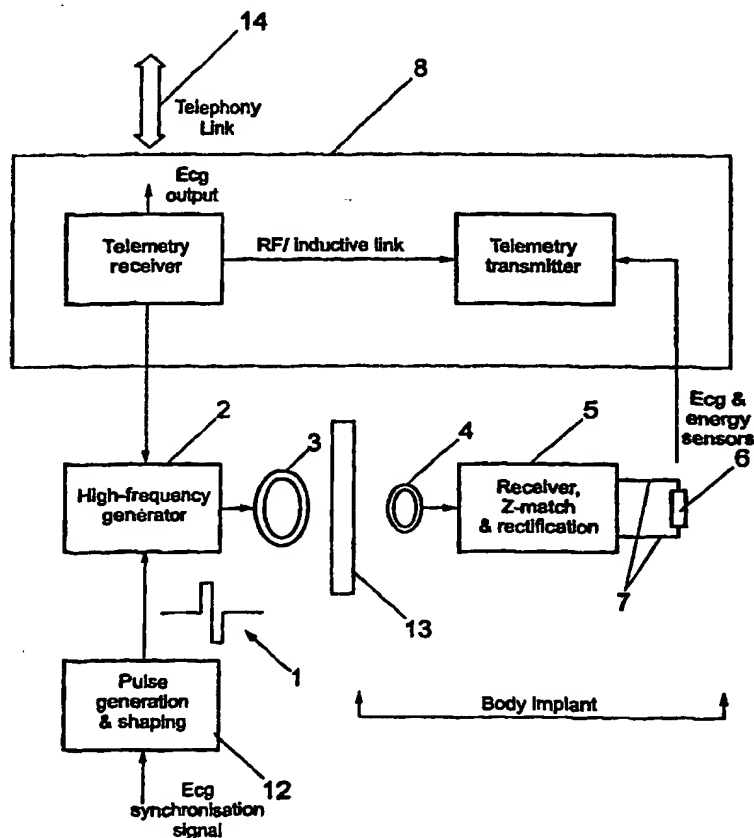
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61N 1/378</b>		<b>A1</b>	(11) International Publication Number: <b>WO 00/67843</b>
			(43) International Publication Date: 16 November 2000 (16.11.00)
(21) International Application Number: PCT/GB00/01725 (22) International Filing Date: 5 May 2000 (05.05.00) (30) Priority Data: 9910323.6                      6 May 1999 (06.05.99)                      GB (71) Applicant (for all designated States except US): UNIVERSITY OF ULSTER [GB/GB]; Faculty of Engineering, Newton-abbey, County Antrim BT37 0QB (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): ANDERSON, John, McCune [GB/GB]; 16 Torgrange, Holywood, County Down BT18 0NG (GB). EVANS, Noel [GB/GB]; 189 Gulladuff Road, Bellaghy, Magherafelt BT45 8LW (GB). (74) Agent: MURGITROYD & COMPANY; Chartered Patent Agents, 373 Scotland Street, Glasgow G5 8QA (GB).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: CARDIAC DEFIBRILLATION

## (57) Abstract

A defibrillator connected by catheters (7) to the heart (6) has an external circuit (2, 12) connected to a passive implanted circuit (5) by transdermal induction via coils (3, 4). For atrial defibrillation, pulses of 3–4J can be transmitted at about 7MHz without damage, using an implanted coil (4) of 20mm diameter.



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1

1     **Cardiac Defibrillation**

2

3     This invention relates to cardiac defibrillation, and  
4     in particular (but not exclusively) to an apparatus for  
5     delivering an electrical defibrillating signal to a  
6     human heart in the state of atrial fibrillation (AF),  
7     using transdermal energy transfer to a passive  
8     implanted device.

9

10    Atrial fibrillation is a common heart arrhythmia that  
11    increases in prevalence with age, with typically 10% of  
12    people over the age of 70 experiencing an incident.  
13    The process of cardioversion of AF to normal sinus  
14    rhythm (SR) has traditionally been attempted by  
15    pharmacological measures or transthoracic direct  
16    current shock. The former has been limited by variable  
17    cardioversion rates and the risk of side effects, in  
18    particular proarrhythmia. The latter requires sedation  
19    or anaesthesia and high energy shocks, and there is a  
20    high recurrence rate. For these reasons, there has  
21    been interest in catheter-based transvenous atrial  
22    defibrillation and its potential use in an implantable  
23    atrial defibrillator. However, atrial implantable  
24    defibrillators are complex devices requiring on-board  
25    pattern recognition with complex recording and follow-



1 up procedures. The need for electrical charging  
2 circuitry using active devices adds to the complexity  
3 and weight of the implant.

4  
5 The present invention provides an apparatus for cardiac  
6 defibrillation which comprises an external circuit and  
7 an implantable circuit; the external circuit including  
8 an induction transmitting coil and signal generating  
9 means for applying radio frequency pulses of  
10 predetermined shape to the transmitting coil; the  
11 implantable circuit including an induction receiving  
12 coil for receiving pulses when the two coils are in  
13 proximity, and a rectification circuit having an input  
14 connected to the receiving coil and an output driving  
15 electrodes implantable in the heart.

16  
17 In a preferred form of the invention, for use in atrial  
18 defibrillation, the power transmitted per pulse is less  
19 than about 5J and the radio frequency is in the range  
20 3-30 MHz, typically about 7MHz.

21  
22 Most preferably, the implantable circuit contains only  
23 passive components.

24  
25 From another aspect the invention provides a method of  
26 cardiac (preferably atrial) defibrillation which  
27 comprises transmitting pulses of controlled shape and  
28 energy transdermally by high frequency magnetic  
29 induction to a substantially passive implanted circuit  
30 which includes electrodes implanted in the heart.

31  
32 It is known to transfer energy transdermally by  
33 induction, but only for purposes of recharging  
34 batteries in implanted devices such as pacemakers or  
35 continuously powering implanted devices such as pumps.  
36 It has not hitherto been proposed to use such

1 techniques to transfer controlled waveforms for high-  
2 energy physiological stimulation.

3

4 An embodiment of the invention will now be described,  
5 by way of example, with reference to the accompanying  
6 drawings, in which:

7

8 Figure 1 shows the elements required for controlled,  
9 transdermal energy delivery to a cardiac load;

10 Figure 2 illustrates the circuitry required external to  
11 the body;

12 Figure 3 represents the body-internal circuitry; and

13 Figure 4 illustrates waveforms in the apparatus.

14

15 In the apparatus (Figure 1), an appropriately  
16 synchronised trigger pulse is firstly generated, based  
17 on the subject's electrocardiogram (ecg). This pulse,  
18 after shaping in a pulse generation and shaping circuit  
19 12 to a waveform 1 suitable for AF conversion, is used  
20 to amplitude modulate a radio frequency (RF) carrier  
21 generator 2 at a power level consistent with the  
22 transmission of 1-5 J of energy to the internal load,  
23 itself nominally 50  $\Omega$  resistive. The transmission path  
24 takes the form of a pair of coaxially-aligned transmit  
25 3 and receive 4 inductors constructed in the form of an  
26 RF transformer. The diameters of the coils 3 and 4 are  
27 set so as to optimise energy transfer at a physical  
28 spacing not less than the thickness of the thoracic  
29 wall 13. Both inductors are wound with enamelled  
30 copper wire. The transmitting coil 3 is mounted on an  
31 insulated paddle to facilitate adjustment in its  
32 placement on the subject's body. The implanted  
33 circuitry is mounted on a printed circuit board and  
34 consists of the receiving coil 4 connected to impedance  
35 matching, rectification and wave-shaping components 5.  
36 The final defibrillating signal is connected to the

1 heart (indicated as an electrical load 6) by catheters  
2 7, one placed in the lateral right atrium (RA) and the  
3 other in the distal great cardiac vein via the coronary  
4 sinus. Alternatively, any conventional atrial  
5 defibrillation delivery system may be used.

6  
7 In one example, the coils 3 and 4 are designed to give  
8 optimum inductive coupling at a centre-to-centre  
9 spacing of 20mm. Given a maximum diameter, for  
10 practicability, of the receiving coil 4 of 35mm, the  
11 transmitting coil 3 has a diameter of 53mm. Both  
12 inductors are wound with 1.5mm enamelled copper wire.  
13 The transmitting coil 3 is arranged as a solenoidal  
14 coil, spaced at one turn. The receiving coil 4 is  
15 pile-wound to conserve space in the final implant.

16  
17 Both inductors in the apparatus are tuned to resonance  
18 at the selected operating frequency of the system,  
19 typically in the range 3-30 MHz. As seen in Fig. 2,  
20 the transmitter uses series tuning by capacitor 9.  
21 Fig. 2 also shows a 50 ohm feed 15 from the generator  
22 2, giving an operational loaded Q of approximately 5.  
23 Referring to Fig. 3, the receiving coil is parallel  
24 tuned, with capacitive matching to the load 6 by means  
25 of capacitors C1 and C2. A radio-frequency choke 11  
26 provides a DC path for rectifier current.  
27 Rectification and shaping is effected in circuit 16.

28  
29 Optionally, as shown in Figure 1 a telemetry link 8 may  
30 be incorporated to provide ecg monitoring and feedback-  
31 derived, automatic tuning of the energy delivery  
32 system. Such a link may also be powered from energy  
33 delivered transdermally, by using a low-power transfer  
34 to power up the telemetry link, or to charge an on-  
35 board battery. Alternatively, the ecg could be  
36 transmitted via the induction coils using a suspended

1 carrier technique.

2

3 As is also indicated in Figure 1, the external  
4 circuitry may include a remote communication link 14,  
5 which may be via telephone communication (landline or  
6 GSM) or via a radio link. This would, for example,  
7 enable the patient's ecg to be transmitted to a  
8 hospital for monitoring and for inspection by a  
9 physician. Defibrillation could be activated remotely,  
10 and spoken instructions could be conveyed to the  
11 patient.

12

13 Atrial defibrillation currently requires a pulse energy  
14 of about 3 to 4J. By using a tuned inductive coupling  
15 as described, typically at a frequency about 7 MHz,  
16 these energy levels can be transmitted transdermally  
17 while maintaining control of pulse shape and timing.  
18 It is contemplated that by refining the pulse shape,  
19 duration and timing required to achieve defibrillation  
20 the energy necessary could be reduced to 1J or less,  
21 which would be painless to the patient and remove any  
22 need for sedation.

23

24 The pulse form 1 shown in Figure 1 is a biphasic pulse,  
25 which is the form we currently prefer. However, other  
26 pulse forms and hence RF envelope shapes may also be  
27 used, such as monophasic and multiple. Fig. 4  
28 illustrates waveforms of the apparatus in more detail.  
29 Fig. 4a is a typical trigger input from an ecg. Fig.  
30 4b shows a typical RF output envelope to the coil 3 as  
31 a single pulse. Fig. 4c shows an alternative RF output  
32 envelope as a burst of two or more pulses. All pulses  
33 can be controlled in width, and the inter-pulse gap of  
34 Fig. 4c is programmable. Each RF pulse, after  
35 transmission and rectification, results in either a  
36 monophasic or a biphasic (baseband) voltage waveform

1 suitable for driving the cardiac load. Fig. 4d shows a  
2 monophasic pulse 17 and a biphasic pulse 18 which can  
3 be produced from the single pulse of Fig. 4a.

4  
5 Although described above with particular reference to  
6 atrial defibrillation, the invention could find use in  
7 ventricular defibrillation. Here, though, the required  
8 energy levels are much higher (typically about 15J).

9  
10 It will be appreciated that one of the benefits of the  
11 embodiment described is that the implanted hardware is  
12 entirely passive and does not require any implanted  
13 power source. However, the invention does not exclude  
14 the possibility of some active components being  
15 implanted, with a reduced requirement for an internal  
16 source of power.

17  
18

## 1 CLAIMS

2

3 1. An apparatus for cardiac defibrillation which  
4 comprises an external circuit and an implantable  
5 circuit; the external circuit including an induction  
6 transmitting coil and signal generating means for  
7 applying radio frequency pulses of predetermined shape  
8 to the transmitting coil; the implantable circuit  
9 including an induction receiving coil for receiving  
10 pulses when the two coils are in proximity, and a  
11 rectification circuit having an input connected to the  
12 receiving coil and an output driving electrodes  
13 implantable in the heart.

14

15 2. An apparatus according to claim 1, for use in  
16 atrial defibrillation, in which the power transmitted  
17 per pulse is less than about 5J and the radio frequency  
18 is in the range 3-30 MHz, preferably about 7MHz.

19

20 3. An apparatus according to claim 1 or claim 2, in  
21 which the signal generating means comprises a radio  
22 frequency generator switched or gated under the control  
23 of a pulse generation and shaping means which in turn  
24 is responsive to an ecg synchronisation signal.

25

26 4. An apparatus according to claim 3, in which the ecg  
27 synchronisation signal is provided via a telemetry  
28 transmitter implanted in the patient.

29

30 5. An apparatus according to any preceding claim, in  
31 which the external circuit further includes a telephony  
32 link by which the ecg may be transmitted to, and/or the  
33 apparatus controlled from, a remote location.

34

35 6. An apparatus according to any preceding claim, in  
36 which the external and implantable circuits include

- 1 impedance matching components to achieve a high degree  
2 of tuning.  
3  
4
- 5 7. An apparatus according to claim 6, in which the  
6 inductive coupling is tuned to resonance.  
7
- 8 8. An apparatus according to claim 8, in which the  
9 inductive coupling is tuned to resonance by use of  
10 series resonance in the external circuit and parallel  
11 resonance in the implantable circuit.  
12
- 13 9. An apparatus according to any preceding claim, in  
14 which the implantable circuit contains only passive  
15 components.  
16
- 17 10. A method of cardiac defibrillation which comprises  
18 transmitting pulses of controlled shape and energy  
19 transdermally by high frequency magnetic induction to a  
20 substantially passive implanted circuit which includes  
21 electrodes implanted in the heart.  
22
- 23 11. The method of claim 10, in which the electrodes  
24 are implanted to provide atrial defibrillation.  
25  
26

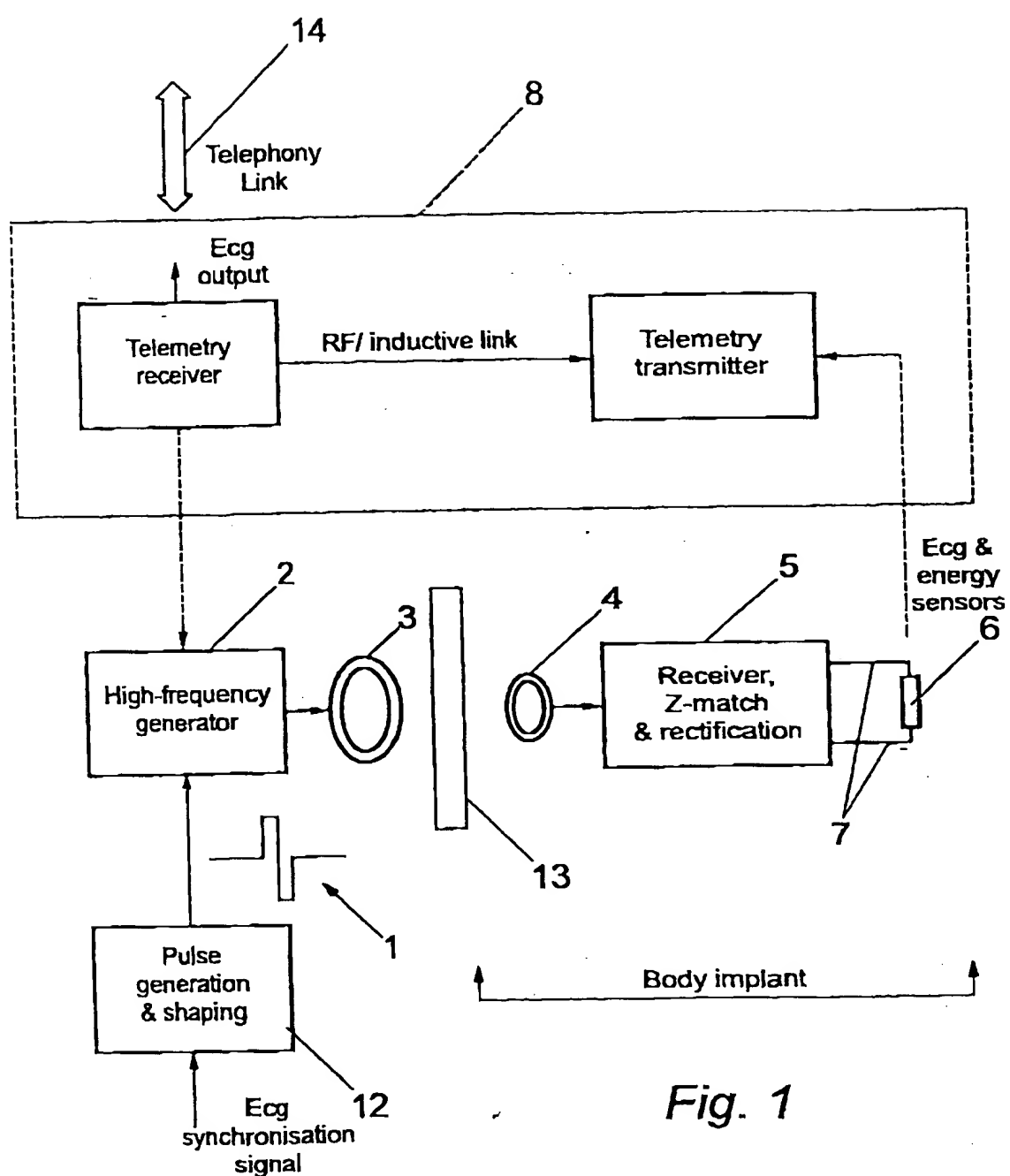


Fig. 1



2 / 3

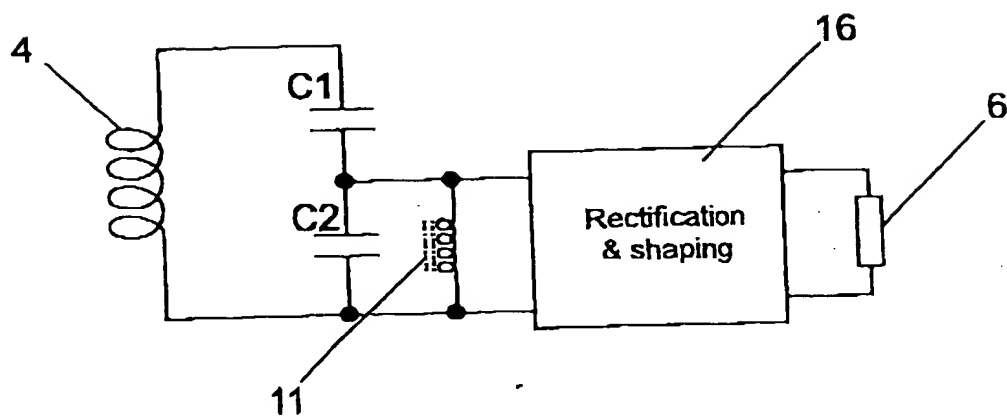
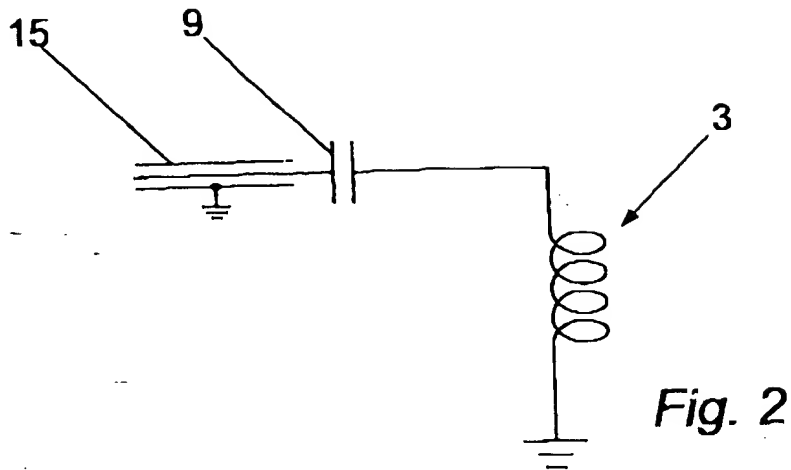
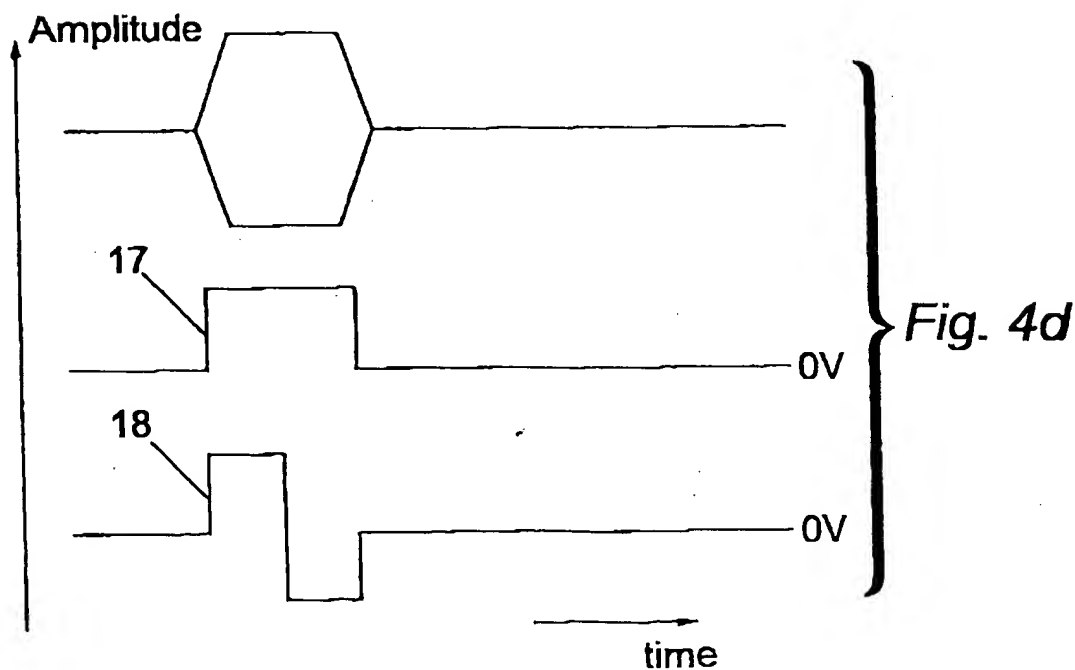
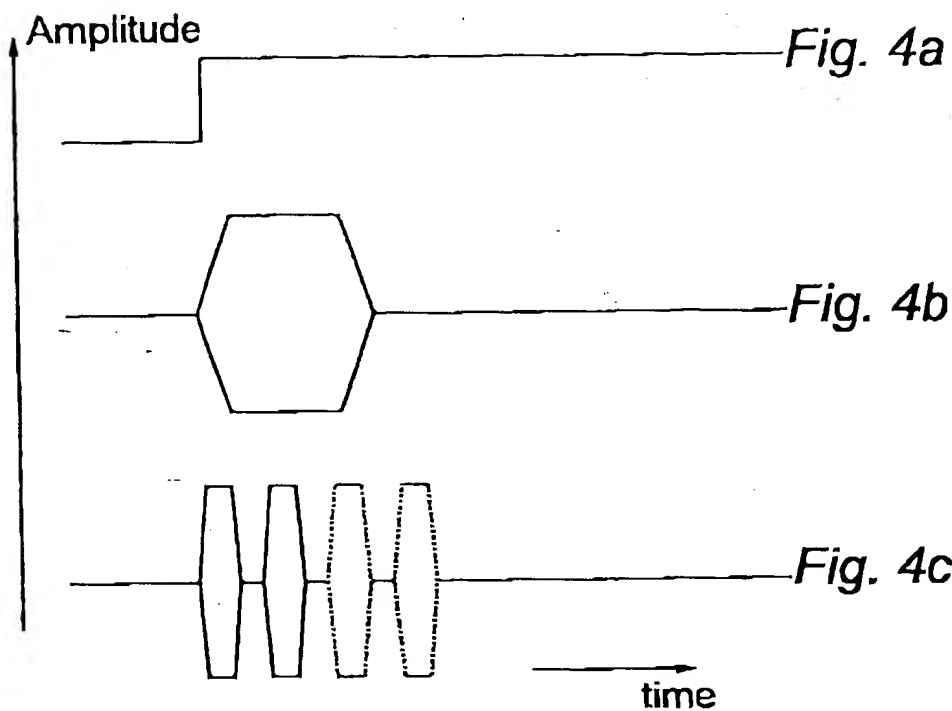


Fig. 3

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# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY  
Chartered Patent Agents &  
373 Scotland Street  
Glasgow G5 8QA  
GRANDE BRETAGNE

**MURGITROYD & COMPANY**

21 MAY 2001

COM **ME**

**PCT**

**NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 17.05.2001

Applicant's or agent's file reference  
P26119A/LMM/MEA

**IMPORTANT NOTIFICATION**

International application No.  
PCT/GB00/01725

International filing date (day/month/year)  
05/05/2000

Priority date (day/month/year)  
06/05/1999

Applicant  
UNIVERSITY OF ULSTER et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

**4. REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Ullrich, C

Tel. +49 89 2399-2322





## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P26119A/LMM/MEA</b>		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. <b>PCT/GB00/01725</b>	International filing date (day/month/year) <b>05/05/2000</b>	Priority date (day/month/year) <b>06/05/1999</b>	
International Patent Classification (IPC) or national classification and IPC <b>A61N1/378</b>			
Applicant <b>UNIVERSITY OF ULSTER et al.</b>			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 3 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input checked="" type="checkbox"/> Certain defects in the international application</li> <li>VIII <input checked="" type="checkbox"/> Certain observations on the international application</li> </ul>			
Date of submission of the demand  <b>15/11/2000</b>		Date of completion of this report  <b>17.05.2001</b>	
Name and mailing address of the international preliminary examining authority:  <b>European Patent Office</b> <b>O-80298 Munich</b> <b>Tel. +49 89 2399 - 0 Tx: 523656 epmu d</b> <b>Fax: +49 89 2399 - 4465</b>		Authorized officer  <b>Schoeffmann, H</b>  Telephone No. <b>+49 89 2399 2625</b> 	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No. **PCT/GB00/01725****I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
- Description, pages:**

1-6 as originally filed

**Claims, No.:**

1-11 with telefax of 26/04/2001

**Drawings, sheets:**

1/3-3/3 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**International application No. **PCT/GB00/01725**☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 10,11.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 10,11.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Yes: Claims 2-9

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB00/01725

	No: Claims 1
Inventive step (IS)	Yes: Claims 2-4,9
	No: Claims 5-8
Industrial applicability (IA)	Yes: Claims 1-9
	No: Claims

**2. Citations and explanations  
see separate sheet****VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
see separate sheet

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
see separate sheet

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01725

ad I:

1. Claim 1 has been amended by adding the passage "and in which the rectification circuit drives the electrodes directly with pulses of a shape which is determined by the signal generating means of the external circuit". The meaning of this passage is unclear (Art.6 PCT) and does not appear to be supported by the original disclosure contrary to the requirements of Art.19(1),(2) PCT.

- Concerning the clarity, this passage appears to be contradictory in itself. Assuming that the external source transmits bipolar pulses as indicated in fig.4b and as explained in the description page 5, last paragraph, these bipolar pulses are received by the implantable coil and the signal is then rectified. Thereby its shape is necessarily altered to a monopolar signal. How can one then say that the shape of the pulses delivered to the heart is determined by the signal generating means of the external circuit. Apparently, the shape of the delivered pulses is determined by the rectification circuit of the implantable circuit.

ad V:

1. In this report reference is made to the following document:

D1... US-A-5 411 537

D2... US-A-3 796 221

D3... US-A-4 549 547

2. Document D2 discloses an implantable apparatus for delivering electrical stimulation energy to a body organ. It is generally known that defibrillation may also be achieved by using low energy stimulation pulses. In that sense, the D2 apparatus is also considered suitable for cardiac defibrillation. The D2 apparatus comprises all constructive features as defined in claim 1:

- an external circuit (48) and an implantable circuit (12, cf. fig.1),
- the external circuit including an induction transmitting coil (32) and signal generating means (fig.3) for applying RF pulses of predetermined shape to the transmitting coil (cf. col.1, lines 40-46);
- the implantable circuit including an induction receiving coil (68) for receiving



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01725

pulses when the two coils are in proximity, and a rectification circuit ((70,72), col.5, lines 16-19) having an input connected to the receiving coil (cf. fig.4) and an output driving electrodes implantable in the heart (cf. figs.4-9).

Accordingly, the apparatus claim 1 in its purely constructive features lacks novelty in view of D2 so that the requirement of Art.33(2) PCT is not met.

3. -The additional features as defined in current dependent claims 5-8 appear conventional in the context of implantable stimulators. Their inclusion in a device as known from D2 does not provide for inventive subject-matter in that it merely amounts to the use of a known feature for its known purpose (Art.33(3) PCT):

claim 5:

A telephone link for transmission of data, eg. ECG data is generally known in the art. the D1 apparatus has a telemetry unit (26) by means of which ECG data may be read into the microprocessor;

claim 6: Impedance matching components, see D1, col.10, line 25: ferrite core;

claims 7,8:

That the inductive coupling is tuned to resonance is obvious when optimisation of energy transfer is required as is the case with the D1 apparatus; that such resonance tuning may be achieved by use series and parallel resonance circuits is generally known to one skilled in the art.

4. The features as defined in claims 2-4 and 9 do not appear to be known in the present context. The use of RF in the range of 3-30MHz does not appear obvious in the context in that D1 suggests 10 to 40 kHz (col.10, lines 25,26) and D3 suggests use of 60 kHz (col.3, line 5). This feature is considered advantageous for a defibrillator when higher pulse energies need to be transmitted transdermally. Claim 2 and claims 3-9 when dependent on the former thus meet the requirements of Art.33 PCT.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB00/01725

ad VII:

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see document D2 and item V.2. above) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, documents D1 and D2 are not identified in the description and their relevant prior art has not been mentioned, although the latter does not apply for D1 in view of page 2, last paragraph of the description of this application.

ad VIII:

1. The description should have been brought into conformity with claim 1. A variance to the invention as defined in the claim 1 appears to exist at page 4, lines 34,35.

04-2001

1 Claims

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1. An apparatus for cardiac defibrillation which comprises an external circuit and an implantable circuit; the external circuit including an induction transmitting coil and signal generating means for applying radio frequency pulses of predetermined shape to the transmitting coil; the implantable circuit including an induction receiving coil for receiving said pulses when the two coils are in proximity, and a rectification circuit having an input connected to the receiving coil and an output driving electrodes which are implantable in the heart; and in which the rectification circuit drives the electrodes directly with pulses of a shape which is determined by the signal generating means of the external circuit.

2. An apparatus according to Claim 1, for use in atrial defibrillation, in which the power transmitted per pulse is less than about 5J and the radio frequency is in the range 3-30 MHz, preferably about 7MHz.

3. An apparatus according to Claim 1 or Claim 2, in which the signal-generating means comprises a radio frequency generator switched or gated under the control of a pulse generation showing means which in turn is responsive to an ecg synchronisation signal.